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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/872,068

05/31/2001

Brian K. Courtney

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07/03/2003

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EXAMINER

KONTOS, LINA R

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 07/03/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/872,068

Applicant(s)

COURTNEY ET AL.

Examiner

Lina Kontos

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3;5-13,15-17;34-38;40-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3;5-13,15-17;34-38;40-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other:

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Drawings

1.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "130" has been used to designate both a lumen and the treatment device (see Figures 3A and 4B). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2.

Claims 1,5,6,9,10,12,13,15,34,35,40,41,44,45 are rejected under 35 U.S.C. 102(b) as being anticipated by Calderon.

Calderon teaches a catheter system capable of delivering an agent to the desired vessel and also means for providing suction. Inflatable occluding element, balloon (38), is provided on outer catheter (60) and is located concentrically around suction catheter (35) and inner infusion catheter (18), each having respective ports for permit injection or extraction of agents to the patient's vasculature, distal to the occluding element. There is an additional infusion port (31) located distal the occlusion balloon. A guidewire (24) is used to assist in insertion of the device,

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as well as a radiopaque contrast agent (column 6, lines 15-17). The device further comprises embolic protection means (22).

3.

Claims 1,2,5,6,9,10,12,15,17 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniels et al.

Daniels et al. teaches a device for infusing a vaso-occlusive material wherein after providing the therapeutic agent, the site can be drained (column 8, lines 1-2) by means of supply port (36) and vent port (38). Outer shaft (16) has supply port (40) that enable communication with its inner lumen, and further has inflation lumen (24) incorporated into its wall. The guidewire (74), extending through inner catheter (68), used during the placing of the device is securely fixed to the distal end of the catheter, and the occluding element (30) may be inflated with contrast agent (column 6, lines 5-6). Catheter (14 or 68) may function as a fluid pathway for infusion of an agent.

4.

Claims 1,6,9,10,11,12,13,15,34,35,40,41,44 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniels et al.

Simpson et al. teaches a catheter device for treatment of disease in a patient's vasculature comprising concentric catheter members (110,112,118) having a proximal expanding sealing member (114). The catheters and their respective lumens allow for the infusion and aspiration of a fluid to the patient wherein means for supplying the fluid is provided through infusion port (column 6, line 61) and means for removing the fluid and other material through aspiration port (column 6, line 66). Infusion port (148) is located distal the occluding device. The device

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further comprises embolic protection means (116) and is capable of delivering a stent to the treatment site (column 7, lines 35-44), and employs the use of a guidewire (156).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5.

Claim 2,15,16 are s rejected under 35 U.S.C. 103(a) as being unpatentable over Calderon in view of Mocoviak et al.

Calderon, as described above, teaches a catheter device with an expandable occluder element and means for providing infusion of a fluid and aspiration to a patient's vasculature, but fails to disclose a sealing mechanism at the distal portion of the catheter.

Mocoviak et al. teaches a perfusion shunt apparatus for isolation and perfusion of an area of a patient's cardiovascular system comprising an expandable occluder (110) with embolic protection means (108). Catheter has inflation lumen (124) embedded in the wall of the outer shaft and may have an additional lumen for receiving a guidewire (column 8, line 27-29) wherein a flexible seal exists on distal end of catheter that flexes to allow the passage of a guidewire while having a fluid-tight seal (column 8, lines 22-26).

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It would have been obvious to one skilled in the art at the time of the invention to incorporate the use of a flexible seal at the distal region of the catheter in order to prevent perfusate from passing through the distal opening.

6.

Claim 3,38 are s rejected under 35 U.S.C. 103(a) as being unpatentable over Calderon in view of Kletchka.

Calderon, as described above, teaches a catheter device with an expandable occluder element and means for providing infusion of a fluid and aspiration to a patient's vasculature, but fails to disclose a separate tube as an inflation lumen.

Kletschka teaches a angioplasty device comprising a balloon (4) having inflation lumen (9).

It would have been obvious to one skilled in the art at the time of the invention to have the inflation lumen not extruded from the wall of the main catheter for simplicity in the manufacturing process.

7.

Claims 7,42 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Calderon in view of Booth et al.

Calderon, as described above, teaches a catheter device with an expandable occluder element and means for providing infusion of a fluid and aspiration to a patient's vasculature, but fails to disclose a foam-filled occluder.

Booth et al., teaches a balloon (98) that is filled with a foam (99) that is in communication with the inflation means for said balloon.

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It would have been obvious to one skilled in the art at the time of the invention to use foam in the balloon allowing the balloon to expand natural expanded state upon the release of applied vacuum pressure.

8.

Claims 8,43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calderon in view of Kletschka as applied to claims 3,38 above, and further in view of Booth.

Calderon, as described above, teaches a catheter device with an expandable occluder element and means for providing infusion of a fluid and aspiration to a patient's vasculature, but fails to disclose a foam-filled occluder.

Booth et al., teaches a balloon (98) that is filled with a foam (99) that is in communication with the inflation means for said balloon.

It would have been obvious to one skilled in the art at the time of the invention to use foam in the balloon allowing the balloon to expand natural expanded state upon the release of applied vacuum pressure.

9.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Calderon in view of Booth et al.

Calderon, as described above, teaches a catheter device with an expandable occluder element and means for providing infusion of a fluid and aspiration to a patient's vasculature, but fails to teach multiple openings on the distal end of the inner catheter.

Booth et al. teaches a catheter for retrograde perfusion comprising an occluding member, (46), and catheter with multiple infusion ports (48).

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It would have been obvious to one skilled in the art at the time of the invention to include multiple infusion ports to allow for a greater delivery rate of the desire fluid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lina Kontos whose telephone number is (703) 306-4207. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

LRK
June 29, 2003


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700